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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ALLEN, MARIANNE P	
ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 01/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/998,189	GOLDMAN ET AL.	
	Examiner	Art Unit	
	Marianne P. Allen	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-24 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-24 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-24 are pending and under consideration.

Priority

The first page of the specification indicates that the instant application is a continuation-in-part of U.S. Patent applications 09/633,824; 09/488,581; and 09/731,978. Provisional application number 60/313,823 and Israel Patent Application IL/132663 are mentioned in the same paragraph. It is unclear whether applicant is trying to claim priority benefit to any or all of these applications as they are not listed on the oath nor in an Application data sheet. Clarification is requested.

Information Disclosure Statement

Applicant is encouraged to file an IDS.

Claim Rejections - 35 USC § 112

Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

Claims 1-13 and 16 are directed to a method of reducing a probability of a negative outcome of application over a population. The steps are obtaining data, analytically processing data, and arriving at a safe and efficacious dosage recommendation. Claims 14-15 are directed to a method of reducing a probability of a negative outcome of application over a population. The steps are obtaining data, analytically processing data, and arriving at an actuarially robust

safe and efficacious dosage recommendation. Claims 17-24 are directed to an apparatus comprising an input and analytical processor.

The specification does not provide guidance on what data to collect commensurate in scope for pharmaceutically active products. The specification does not make clear how to process data to relate dosage data to subgroupings. It does not provide guidance on how to determine what the subgroupings should be.

The final positive, active step of the methods is to arrive at a dosage recommendation. The specification defines a negative outcome on page 15 to be limited to failure to receive regulatory approval, withdrawal of drug from the market, narrowing of a drug target population after being marketed. It is unclear how a dosage recommendation in and of itself will accomplish any of these goals. As such, the claims appear to be missing critical steps to enable the claimed methods and apparatus.

As such, the claimed method and apparatus are considered to be an invitation to experiment.

Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 14 recite in the preamble "application over a population, of a pharmaceutically active product" and the body of the claim refers to obtaining "dosage data and result data of said application." The claim does not make clear that data for a population, including subgroupings within the population, is being collected. It is not known what the metes

and bounds of "result data" are. It cannot be determined what information would meet this limitation or be excluded by it. The final positive, active step of the methods is to arrive at a dosage recommendation. It is not known how one of ordinary skill in the art "arrives" at a dosage. This term does not appear to be an art understood term indicating specific positive, active steps. Note that "being arrived at to minimize said probability" is not considered to be a positive, active step. These steps are not consistent with the preamble goal of "reducing a probability of a negative outcome." The specification defines a negative outcome on page 15 to be limited to failure to receive regulatory approval, withdrawal of drug from market, narrowing of drug target population after being marketed. It is unclear how the dosage recommendation in and of itself will accomplish any of these goals. Claim 17 is similarly unclear.

It cannot be determined from the specification what is considered to be a pharmaceutically active product. For example, is coffee or chocolate intended to be embraced by the claims?

It cannot be determined from the specification what is considered to be a safe dosage or an efficacious dosage. These are relative terms with no frame of reference provided (e.g. safe so it doesn't kill you or safe so there are no side effects?).

It cannot be determined from the specification what is considered to be an actuarially robust dosage.

Claim 2 refers to "standard pharmaceutical product tests" and claim 3 refers to "non-standard pharmaceutical product tests." It is unclear what features define these categories such that one of ordinary skill in the art would be able to discriminate.

Claim 5 recites "pharmaceutically active products similar to said product." However, the degree of similarity or the particular activities that must be shared cannot be determined. For example, is chocolate sufficiently similar to valium (structurally, functionally, or otherwise) for this pair to be embraced by the claim? Note that the historical data of the multiple products does not have to be of the same type. That is, the historical use data of chocolate as it effects depression could be obtained and the historical use of valium to treat anxiety. It is unclear how disparate information would be compared to result in the desired goal.

Claim 6 is confusing in that it appears that the step set forth must implicitly be part of independent claim 1 in order for the analytical processing to occur. Clarification is requested.

Claim 7 is confusing in that it appears that the step set forth must implicitly be part of independent claim 1 in order for the analytical processing to occur. Clarification is requested.

Claim 11 is confusing in that claim 1 does not require collecting the particular type of data used by the named techniques. In addition, the named techniques do not appear to reflect techniques with art understood definitions. That is, what are the metes and bounds (with respect to the required positive, active steps or algorithms or data structures, etc.) for a "decision making optimization technique?" See also claims 15 and 17.

Claim 17 requires an analytical processor. It is unclear if this is intended to be a particular piece of hardware or software or hardware programmed to perform a particular task. The recitation "for analytically processing..." is considered to be an intended use that does not clearly limit the processor.

Claim 18 is unclear in reciting that the analytical processor is "further operable." This does not clearly provide a structural or functional component that differs from that of claim 17.

Claim 19 is unclear in reciting "a thresholder." This does not make clear if this is a piece of hardware or additional software and what particular structure it must have or function it must perform.

Claim 20 doesn't appear to limit the apparatus of claim 19 as the limitation concerns the value of the data. This would not change the structure or function of the apparatus in the same way that the structure and function of a camera is not changed when a picture is taken of a cat compared to a dog.

Claim 24 is confusing in its recitation "to facilitate ownership transfer in case of occurrence of said negative outcome." It is unclear if this is intended to provide a limitation for a particular kind of memory unit or additional hardware/software for the recited transfer.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the

reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-4, 6-10, 14, and 17-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Classen (U.S. Patent No. 6,219,674).

Classen discloses a method and apparatus for using product data to enhance the safety of products. Data is analyzed regarding adverse effects for population subgroups. Intellectual property information can be included in the assembled data. Analysis can be performed with respect to amount, duration and timing of exposure to the product (e.g. dosage) and dosages for new conditions and/or subgroups recommended. The intent of the disclosed invention is to reduce unforeseen adverse events. See at least abstract; claims; column 3, lines 54-65; columns 5-6, bridging paragraph; column 6, lines 39-54; and Figures 4-6. Absent a specific definition of "actuarially robust" (see for example, claim 14) it is presumed that the prior art dosage recommendations meet this limitation.

Claim Rejections - 35 USC § 103

Claims 11-13, 15-16, and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Classen (U.S. Patent No. 6,219,674).

Classen is applied as above but does not specifically disclose the recited techniques.

However, Classen discloses that any suitable programming to accomplish the task may be used and the instant specification appears to indicate that the recited techniques are all well known methods of data analysis. As such, it would have been obvious to use the known

techniques for analysis in the system of Classen in order to provide the desired analysis of determining dosages to avoid adverse effects.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-0722. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Marianne P. Allen
Primary Examiner
Art Unit 1631

mpa